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| Applicant(s) | : | Thomas S. Parker, et al. |
| Serial No. | : | 08/432,691 |
| Filing Date | : | May 2, 1995 |
| For | : | METHODS USEFUL IN ENDOTOXIN PROPHYLAXIS AND THERAPY |
| Group Art Unit | : | 1200 |
| Examiner | : | Kimberly Jordan |

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October 3, 1995

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

**AMENDMENT UNDER 37 C.F.R. §1.111**

S I R :

This is submitted in response to the Office Action dated August 30, 1995. The examiner indicated that claims 27 and 31 were objected to, but are presumably allowable, and that claims 23-26 and 28-30 were rejected in view of Morton et al. The examiner provided a computer generated abstract of Morton in the action. Applicants have studied the action carefully, and have secured a full copy of the Morton reference, a copy of which is attached.

Reconsideration is requested, for the reasons now set forth.

The Morton paper, in the abstract, discusses compositions containing "up to 2 mole % TG," i.e., "TG" is triglyceride. In

fact, while Morton's final product may contain 2 mole % TG, some of the compositions actually start higher, as per Table 1, e.g., where 300 nmol of TG were used in a starting material.

Attached hereto is a calculation sheet to show how mole % corresponds to weight %, the actual parameter used in the claims (i.e., 7% by weight). It will be seen that the Morton compositions actually contain about 2.6-3.0 weight % of triglyceride.

This value is significantly below what is claimed (7%), and it is recognized that the rejection is under 35 U.S.C. §103, not 35 U.S.C. §102. For an obviousness rejection to be proper, however, there must be some motivation to modify the prior art to arrive at what is claimed. As will be shown, Morton does not provide the requisite motivation.

Figure 9 of the Morton reference deals with the abilities of the Morton compositions to transfer lipids, which is the utility envisioned in the paper. The curve flattens at about 0.4 mole % of cholesteryl ester, which is 20% of a 2.0 mole % composition, i.e., substantially lower.

Morton implies functional equivalence of cholesteryl ester (CE) and triglyceride (TG), as per the abstract: "up to 2 mole % TG and/or CE." Note that at page 1561, end of "Characterization of Liposome Substrates," Morton et al. speak of "data similar" to that obtained for CE being obtained for TG, and that these data are not shown.

In preparing pharmaceutical compositions, there is always an interest in administering or using the lowest dose or amount of active compound possible. According to Morton et al., CE provided optimal results at about 0.4 mole %, and TG (a neutral lipid), is similar to CE in an equivalent system. Why would anyone push the amount of neutral lipid in a composition up, if the desired effect is achieved at a lower range? The fact of the matter is, while there is general motivation to lower dosages, there is no reason to increase them, unless of course a different purpose is involved. Morton does not deal with treatment of endotoxemia, does not mention it, and certainly does not suggest it. Without that information, one cannot glean a suggestion to move a 2.3 weight percent composition up to about 7.0 weight percent, the lower limit of the claims.

In short, the claimed subject matter is not suggested by the prior art. The examiner is asked to reconsider her rejection, withdraw it, and allow the subject application.

Respectfully submitted,

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